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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/813,980

03/31/2004

Edward Wells Knowlton

KNW-0018

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77845

7590

03/16/2009

Goodwin Procter LLP

Attn: Patent Administrator

135 Commonwealth Drive

Menlo Park, CA 94025-1105

EXAMINER

SWEET, THOMAS

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

03/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/813,980	Applicant(s) KNOWLTON, EDWARD WELLS	
	Examiner Thomas J. Sweet	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/15/2008 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-39 have been considered but are moot in view of the new ground(s) of rejection. The Examiner disagrees with the applicant's remarks but rejection on new grounds to clarify the interpretation of the claims and reinforce the rejection.

Response to Amendment

The declaration under 37 CFR 1.132 filed 12/15/2008 is insufficient to overcome the rejection of claims 1-39 based upon the opinion that template and compression does not sufficiently remodel as set forth in the last Office action because: Any remodeling is sufficient to meet the claim language and this is opinion rather than evidence.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the pre-positioning the selected tissue by hand, suturing the tissue in place, using a steri strip, using a surgical/tissue adhesive, or using

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a surgical clamping device known in the art must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 30 and 39 include improper alternatives not presented in the accepted Markush format of “selected from the group consisting of” a, b, c “and” d. Claimed alternatives

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are only allowed in a Markush claim which is a genus encompassing the alternatives (i.e. one limitation defined by a group of member to that limitation). In the claimed format the group is unbounded and indefinite.

Claims 1-39 (1, 30, 39) contains the trademark/trade name Steri-stripTM. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an adhesive strip and, accordingly, the identification/description is indefinite.

The use of the trademark Steri-stripTM has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 14-24, 26-29, 31-40 and 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Knowlton (US 6,350,276) with the intrinsic evidence of Dressel or in view of Dressel (US 4985027). Knowlton discloses a method of energetically treating a target tissue site (col 11-12, thermal), the method comprising: pre-positioning tissue in a aesthetically (background on the invention, such as line 40-42 and inherent positioning of the patient for access) correct configuration (cols 19-20, lines 62-3, contact and pressure are required otherwise there is no current flow) wherein prepositioning of the selected tissues (via inherent surgical positioning to access and work on the cite, disclosed liposuction a pretreatment including positioning, the conforming template which is prepositions prior to energetically treating and the template “can be separate” therefore perpositioned “with the energy delivery device”, col 13, lines 48-50) is used to shape a thermal lesion so as to create or facilitate the creation of a directed wound healing response (i.e. the lesion is formed on moved tissue); and wherein vectored pre-positioning of the selected tissues is accomplished using surgical techniques, including but not limited to, pre-positioning the selected tissue by hand (liposuction is prepositioning and inherently includes positioning by hand as

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shown in fig. 10 and col 5 lines 59-63), suturing the tissue in place, using a steri strip (trade mark), using a surgical/tissue adhesive, or using a surgical clamping device known in the art (such as 12, figs. 1, 13, 14 and 17 and braces fig. 15 in which the template can be can be separate from the energy delivery device);

delivering energy to the tissue site using an energy delivery device (col 12, lines 5-11);
delivering a vectored mechanical force to the tissue site (col 12, lines 5-11);

producing a thermal adhesion or lesion at the tissue site (i.e. cleave of collagen crosslinks); and

remodeling at least a portion of tissue at the tissue site (to achieve a smoother contour).

With regard to claims 2 and 3, inherently a patient is pre-positioned for treatment (e.g. a patient is placed on an operating table, standing, etc...) in conjunction with the treatment.

With regard to claims 22, 33, 37 and 39, selecting the tissue site based on an amount of convexity at the tissue site (inherent to smooth the contour).

With regard to claims 4-7, 31, 35-36, 38 and 40-42, producing a plurality of adhesions or lesions is substantially continuous or at least partially overlapping and delivering energy in a selected pattern (Col 6, lines 5-48, discontinuous modes/pattern of application, specifically lines 22-23 states power is pulsed which is overlapping and a pattern).

With regard to claim 8, the force is a substantially uniform force applied over the tissue site (col 12, line 17).

With regard to claims 9-10, force profile with respect to a radial direction of a force application surface, the force profile substantially increasing in an inward direction with respect to an edge of the force application surface (col 17, lines 8-22- the tissue interface inherently

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applies this force profile by having radiused edges and as described in the paragraph from col 18-19)

With regard to claim 11, delivering a first force in a first direction and delivering a second force in a second direction (col 12, lines 17-24).

With regard to claim 14, pre-positioning tissue at the tissue site substantially prior to energy delivery to shape the tissue adhesion or lesion or create a directed wound healing response (the disclosed bipolar RF energy system requires contact with the skin to work and the tensioning device 16 is separate from the electrodes 18 which pre-contact the tissue as the electrode are brought into contact with the tissue).

With regard to claims 15-16, 19, 34 and 38, cooling a layer of tissue or a surface layer of tissue of at least a portion of the tissue site (col 4, lines 7-9) and producing a reverse thermal gradient within at least a portion of the tissue site (col 5, lines 52-59) which preserves at least a portion of a surface, a tissue layer or an epidermal layer at or adjacent the tissue site.

With regard to claims 27 and 29, performing a liposuction procedure substantially at the tissue site (col 1-2, lines 54-16).

With regard to claim 28, skeletonizing at least a portion of fibrous septae at the tissue site (an unintended side effect as discussed in Col 12 lines 34-49).

Claims 12, 13, 25, 30 and 41 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Knowlton with the intrinsic evidence of Dressel or in view of Dressel (US 4985027). Knowlton discloses a method of energetically treating a target tissue site as discussed above including a positive force (positive pressure, greater than zero). Knowlton anticipated and clearly envisaged the range (range of .01- 10 ... 2.5-

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10 lbs) by having a range (greater than zero) overlapping the claimed ranges. It this does not establish sufficient specificity. Applicant has not disclosed that having force in the claimed ranges solves any stated problem or is for any particular purpose. Moreover, it appears that the method would perform equally well with any positive force up to the point of tissue destruction. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the range of 2.5-10 lbs because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Knowlton.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Thomas J Sweet/

Primary Examiner, Art Unit 3774